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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,068	05/04/2007	Fong Poh Lisa Ng	033946-1401	6103

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,068	NG ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-32 and 45-48, drawn to methods for the alteration of the load of a hepatitis virus in a host organism comprising the modulation of a complex formed between hnRNP K and a regulatory region in the viral genome.

Group II, claim(s) s 33-44, drawn to in vitro methods for the identification of compounds capable of altering the formation of the hnRNP K/viral genome complexes.

Group III, claim(s) 49-51, drawn to methods for diagnosing hepatitis viral infections comprising the use of a compound of claim 49.

Group IV, claim(s) 52, drawn to a method for evaluating a hepatitis infection comprising the use of two nucleic acids comprising the enhancer II region of HBV DNA, one of which does not comprise an adenine in position 1752.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of these groups is the use of a modulator of HN-RNP K binding to the Hepatitis B virus genome as a means for altering the load of HBV. The teachings of the application indicate such modulation may be through any means (i.e. indirectly or direct modulation). See e.g., page 7 (indicating that various means for modulation of hnRNP K HBV genome complexes may be used). Thus, the claims broadly read on any method for the modulation of a hepatitis viral load in a patient through administration of a compound that directly or indirectly modulates hnRNP K binding with a hepatitis virus genome.

The art teaches that Interferon-alpha is used to treat HBV infections, although the mode of the anti-viral activity is not known. See e.g., Rang et al., JBC 277:7645-47. The reference makes no mention of hnRNP K or its interaction with the viral genome. However, it is noted that later teachings in the art indicate that a protein known as A3B suppresses HBV replication through inhibiting the binding of hnRNP K to the enhancer II region of HBV. See e.g., Zhang et al., Cell Microbiol 10:112-121. The art also teaches that A3B is up-regulated in hepatic cells in response to interferon-alpha. Bonvin et al., Hepatol 43:1364-74. Thus, the teachings in the art indicate that upon stimulation with interferon-alpha, hepatic cells up-regulate A3B, which then acts as an inhibitor or hnRNP K binding to the HBV genome, thereby inhibiting viral transcription and altering the load of the virus in the patient.

In view of the A3B up-regulation by interferon-alpha in hepatic cells, the teachings of the later art indicate that the interferon-alpha administration of the Rang reference would inherently have resulted in the modulation of HBV through the mode required by the claims. Thus, as the present claims read on the method of treatment described by Rang, the claims lack unity over the prior art.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I above, the Applicant is required to elect

- One of the hepatitis viruses of claim 2.

- An embodiment of claim 3 wherein the host organism is a microorganism (e.g., a cell from a hepatic cell line- claims 3 and 16-19) or is a mammal (claims 3 and 4).

  If microorganisms are elected, Applicant is further required to elect a cell line from claim 19.

  If mammals are elected, Applicant is further required to elect a mammal of claim 4

- An embodiment of the claims method, wherein the method is

  An in vivo method for the identification of a suitable compound to modulate the indicated complex (claims 10-15), or

  A method for the treatment of a hepatitis infection (claims 45-48).

- An embodiment wherein the complex formation is modulated through the use of

  (a) a DNA molecule (claims 20-22),

  (b) an RNA molecule (claims 20-23),

  If an RNA molecule is elected, the Applicant is required to elect one of an aptamer (claims 22 and 45), a miRNA (claims 22 and 45), or a siRNA (claims 22, 23, and 45); and if siRNA is elected, Applicant is further required to elect one of the sequences of claim 23.

  (c) a compound that alters the degree of phosphorylation of hnRNP K (claims 25 and 45),

  (d) a compound that alters the intracellular quantity of hnRNP K (claims 26 and 45),

  (e) an agonist of a cell receptor (claims 27-32 and 45-46), or

(f) an antagonist of a cell receptor (claims 27-32 and 45-46).

If either of (e) or (f) is elected above, Applicant is required to elect one of the receptors of claims 30, and one of the proteins of claims 32 or 50.

For Group II above, the Applicant is required to elect one of the modes of detection identified in claim 35.

For Group III above, the Applicant is required to elect an embodiment of the claimed method wherein the compound is identified as

an aptamer (claim 49),

a miRNA (claim 49),

an siRNA (claim 49),

a compound that alters the degree of phosphorylation of hnRNP K (claim 49),

a compound that alters the intracellular quantity of hnRNP K (claim 49),

an agonist of a cell receptor (claims 49 and 50), or

an antagonist of a cell receptor (claims 49 and 50).

If the Applicant elects either an agonist or an antagonist of a cell receptor, the Applicant is required to elect one of the receptors of claim 50.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species as indicated in the listing above.

The following claim(s) are generic: Claim 1 is generic for Group I. Claim 33 is generic for Group II. Claim 49 is generic for Group III.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the claims lack unity for the same reasons as indicated with respect to the Group above, and as each of the indicated species relates to different viruses, compounds, or compositions which share no common special technical feature over the prior art.

Conclusion

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648